UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF WEST VIRGINIA

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U.S. DISTRICT COURT
Northern District of WV

STEVEN M. RECHT; ALESHA BAILEY; And STEPHEN P. NEW, Plaintiffs, v. JIM JUSTICE, *in official capacity as Governor of West Virginia;* and PATRICK MORRISSEY, *in official capacity as Attorney General of West Virginia,* Defendants.	)	Case No. 5:20-CV-90 (Bailey) COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

CHALLENGING CONSTITUTIONALITY OF STATE LAW

Plaintiffs, Steven M. Recht, Alesha Bailey and Stephen P. New, by and through counsel, for their Complaint against Defendants Jim Justice and Patrick Morrissey, in their official capacities, as displayed in the case caption above (collectively, Defendants), state as follows:

SUMMARY OF THE CASE

1. West Virginia, and the United States more generally, currently struggle in the midst of a life-threatening pandemic and a continuing opioid crisis. While neither is likely a permanent condition, health problems place a premium on assuring that the people receive truthful and accurate information about their health, the drugs and medical devices available to treat them, and their legal rights

when injured by these treatments, so that they can make informed judgments about their care and about their remedies when treatments go wrong.

2. Like all other information, health information exists in the marketplace of ideas, which serves, under the "theory of our Constitution," as that the best way to discover the truth from which the people's "wishes safely can be carried out." *Abrams v. United States*, 250 U.S. 616, 630 (1919) (Holmes, J., dissenting).

3. This Action for injunctive and declaratory relief, brought under 42 U.S.C. § 1983, challenges the constitutionality of the disingenuously titled "Prevention of Deceptive Lawsuit Advertising and Solicitation Practices Regarding the Use of Medications Act" (the Act), recently approved and due to go into effect on June 5, 2020. If implemented, the statute would prohibit consumers from getting accurate information, necessary for their health, about problems with drugs and devices marketed to them and their physicians. It would hamper receipt of information about legal rights by restricting truthful, non-deceptive attorney advertising, and it would burden those communications with unnecessary and unjustified disclosures, while forbidding the use of certain language or images. *See* W. Va. Code § 47-28-1 *et seq.* Moreover, it would generate consumer confusion.

4. The new statute deems a knowing and willful failure to include certain mandatory disclosures "an unfair and deceptive act or practice in violation of § 46A-6-101 *et seq.* of this code" (*i.e.*, West Virginia's Consumer Credit and Protection Act).

5. Yet, as described further below, the potential enforcement of these provisions would deprive consumers of truthful and important information in violation of the First Amendment.

6. The First Amendment to the United States Constitution protects consumer access to truthful and non-deceptive information conveyed through commercial speech.

7. The First Amendment protects truthful lawyer advertising.

8. The First Amendment further requires the constitutionally proper regulation of lawyer advertising to be narrowly tailored to achieve a substantial State interest

9. The Fourteenth Amendment's Equal Protection Clause is also implicated by the types of regulations at issue in this Action because a government regulation that discriminates among speech-related activities must "be finely tailored to serve substantial state interests, and the justifications offered for any distinctions it draws must be carefully scrutinized." *Carey v. Brown*, 447 U.S. 455, 461-62 (1980).

10. Here, the prohibitions and disclosure requirements are unjustified by the State's purported interest, fail the narrowly tailored requirement, prohibit the communication of truthful, non-deceptive information, suffers from vagueness and overbreadth, and unreasonably burden protected commercial speech in unjustifiable and discriminatory ways. For these reasons, the statute is unconstitutional.

PARTIES

11. Plaintiff Steven M. Recht is a licensed West Virginia lawyer who practices from the Recht Law Offices, 3405 Main St, Weirton, WV 26062, the locality where he grew up.

12. Plaintiff Recht is active in West Virginia's legal associations, including service as a member of the board of governors of the West Virginia Association for Justice and as immediate past president of the Hancock County Bar Association.

13. Plaintiff Recht's legal practice includes representing plaintiffs injured by dangerous drugs and defective medical devices.

14. Plaintiff Recht has used advertising to inform the public about his practice and their rights.

15. Plaintiff Recht maintains a website for his law firm (https://www.rechtlaw.com/).

16. The website covers various areas of law that are part of his legal practice, including those subject to the Act's restrictions and requirements, and informs viewers that about "[s]ome prescription drugs that have been shown to present particular danger" and "[s]ome of the defective medical devices at the center of lawsuits." *See* https://www.rechtlaw.com/personal-injury-lawyers/product-liability/#drugs.

17. Plaintiff Recht believes that some of his potential clients in West Virginia will receive television advertising from law firms located in Pittsburgh that will not be subject to the restrictions and requirements of the Act and are likely to

find that advertising unencumbered by prohibitions or disclaimers imposed by the Act to be more informative and therefore the law firms sponsoring those advertisements more attractive to handle their cases.

18. Plaintiff Recht is uncertain of his rights as to what the Act defines as legal advertisements in light of the Act's prohibitions and requirements.

19. Plaintiff Alesha Bailey, of Welch, McDowell County, West Virginia, is a consumer of legal services who started taking the drug, Invokana, around November 2018 for Type 2 Diabetes.

20. Later that month, Plaintiff Bailey suffered a fall after feeling dizzy.

21. She continued to suffer unusual symptoms, which she reported to her doctor, until she discovered a spot on her genital area that proceeded to get worse and prompted her to go to the Welch Community Hospital emergency room.

22. Plaintiff Bailey was transported by ambulance to Raleigh General Hospital, where she was diagnosed with gangrene and underwent surgery to drain the abscess.

23. Despite the surgical care she received, Plaintiff Bailey went into septic shock, underwent three additional surgeries to drain the infection, and received

around-the-clock antibiotics. Ms. Bailey also suffered kidney failure, which required dialysis.

24. Plaintiff Bailey has no memory of the procedures performed on her while she was in septic shock.

25. After her stay at Raleigh General Hospital, Plaintiff Bailey stopped taking Invokana.

26. In May 2019, Ms. Bailey's sister, Denise Bailey Iofalla, who serves as Secretary to Judge Randolph J. Murkensky of the Circuit Court of McDowell County, West Virginia, was watching television when she saw an advertisement

about the adverse effects some people have when taking Invokana and mentioned genital gangrene as one of those effects.

27. Following her viewing of the advertisement, Ms. Iofalla got in touch with attorney Stephen P. New about making a claim about Invokana.

28. Plaintiff Bailey believes she would not have realized the connection nor pursued her legal rights without that legal advertisement.

29. Plaintiff Bailey is uncertain about her rights to receive information about drugs and medical devices without the prohibitions and burdens imposed by the Act.

30. Plaintiff Stephen P. New, a licensed attorney and life-long resident of West Virginia, is the principal in the law firm of Stephen P. New, L.C., d/b/a New, Taylor and Associates, with offices at 114 Main Street, Beckley, WV 25801.

31. Plaintiff New has advertised his practice and, in October 2018, he began marketing his practice to consumers of legal services whose children were affected by the opioid epidemic throughout West Virginia and other states.

32. In February 2019, Plaintiff New and his firm engaged in a statewide television marketing campaign to raise awareness of the opioid epidemic and the legal rights of infant children who have been diagnosed with Neonatal Abstinence Syndrome (NAS) as well as the rights of their parents or guardians.

33. Thereafter, Plaintiff New and his law firm commenced a television advertising campaign, along with a digital marketing campaign throughout the

United States, as part of a team of lawyers representing NAS-addicted children.

West Virginia has been ground zero for the opioid crisis and has more children per capita in the custody of a non-parent than many other states. Like thousands of children born every year, West Virginia babies were and are born addicted to opioids. Prenatal exposure to opioids cause severe withdrawal symptoms and lasting developmental impacts. The first days of these babies' lives are spent in excruciating pain as doctors wean the infants from opioid addiction. Plaintiff New's clients, these NAS-addicted babies, will require years of treatment and counseling to deal with the effects of prenatal exposure. Plaintiff New's clients are the innocent victims of the opioid crisis that has ravaged West Virginia and Appalachia in particular, and the entire United States of America, generally.

34. One of his advertisements for parents or guardians of NAS-addicted children begins with the word, "Attention."

35. Plaintiff New's marketing to consumers through legal advertisements, particularly those affected by the opioid crisis in West Virginia, continues through present. He also plans to continue advertising in the future.

36. Plaintiff New's advertisements have not previously included the disclaimers required by the Act.

37. Plaintiff New also engages in digital marketing and advertises in social media, such as Twitter or Facebook.

38. Plaintiff New also maintains a website for his law practice

(https://newtaylorlaw.com/), which the Act treats as a legal advertisement.

39. On his website, Plaintiff New indicates he handles cases involving defective drugs and medical devices and informs viewers that he provides information for "Opioid Claims for Addicted Babies" and "Zantac® Claims in Beckley, WV."

40. Plaintiff New continues to want to advertise his legal services and maintain his website, but the Act purports to impose unconstitutional conditions upon that advertising, and Plaintiff New is uncertain about his rights in light of the enactment and imminent implementation of W. Va. Code § 47-28-1 *et seq.*

41. Defendant Jim Justice is sued in his official capacity as Governor of West Virginia, and is located in Charleston, West Virginia.

42. The West Virginia Constitution vests the State's "chief executive power" in Governor Justice, who is charged to "take care that the laws be faithfully executed." W. VA. Const. art. VII, § 5. Under this affirmative requirement of the Constitution, the Governor must, consistent with his oath of office, utilize all the power at his command to require the execution of the valid laws, which the Legislature has passed. In short, he is the chief executive of West Virginia and charged with carrying out the State's laws.

43. Defendant Patrick Morrissey is sued in his official capacity as Attorney General of West Virginia, and is located in Charleston, West Virginia.

44. Pursuant to state law, Attorney General Morrissey is the State's chief law enforcement officer and is responsible for investigating and prosecuting

violations of state law, as well as, commencing legal actions on behalf of the State. In that capacity, he is entrusted with enforcing the laws of the State as they relate to, among other things, consumer protection and unfair trade practices. Attorney General Morrissey is specifically tasked with enforcement of West Virginia's Consumer Credit and Protection Act. *See* W. Va. Code § 46A–7–104. He and his office would be responsible for enforcing the statutory provisions at issue in this case.

JURISDICTION AND VENUE

45. This is an action for injunctive and declaratory relief pursuant to 42 U.S.C. § 1983 against enforcement of the new legal advertisement statute grounded on the First and Fourteenth Amendments to the United States Constitution. Jurisdiction exists pursuant to 28 U.S.C. § 1331 and 1343 based on 42 U.S.C. § 1983 and questions of federal constitutional law. Jurisdiction also exists under the Declaratory Judgment Act, 28 U.S.C. §§ 2201(a) and 2202. This is both a facial and as-applied constitutional challenge to the statute.

46. This Court has personal jurisdiction over the parties because all parties are located in West Virginia and the relevant acts occurred or will occur in West Virginia.

47. Venue is proper in this district pursuant to 28 U.S.C. § 1391, as a substantial part of the events or omissions that give rise to an enforcement action under the challenged Act and any enforcement itself against Plaintiffs would occur in this district.

INTRODUCTION

48. Attorney advertising constitutes a form of commercial speech entitled to First Amendment protection. *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977).

49. The First Amendment protects commercial speech "based on the informational function of advertising." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 563 (1980).

50. Undue restriction of advertising "reduces the information available for consumer decisions and thereby defeats the purpose of the First Amendment." *Id.* at 567.

51. Therefore, the right infringed is not just the right of the speaker to communicate, but the right of consumers and the general public to receive the information. *See Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 757 (1976) ("If there is right to advertise, there is a reciprocal right to receive the advertising.").

52. Although the Act is aimed at deceptive and misleading advertising, it is overbroad in prohibiting or otherwise restricting advertising and communications that are not deceptive and misleading.

53. The Act is additionally vague in signifying what speech violates the statute and is not limited to furthering a substantial state interest.

54. Both the likelihood of enforcement and the threat of enforcement unconstitutionally chill the exercise of protected free speech rights, including

Plaintiff New's and Plaintiff Recht's plans to engage in truthful and nondeceptive advertising, and Plaintiff Bailey's willingness to receive that advertising.

55. A federal court may enjoin a state officer from taking future actions that violate federal law and may take prospective actions to assure compliance with constitutional requirements. *Ex Parte Young*, 209 U.S. 123 (1908).

56. This action seeks urgent declaratory and injunctive relief for injuries caused by and likely to be caused by West Virginia's newly enacted legal-advertising law, because the "loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Elrod v. Burns*, 427 U.S. 347, 373 (1976).

THE NEWLY ENACTED LEGAL-ADVERTISING LAW

57. On March 7, 2020, the Prevention of Deceptive Lawsuit Advertising and Solicitation Practices Regarding the Use of Medications Act (the Act) was signed into law by Defendant Justice. It takes effect on June 5, 2020.

58. The Act regulates permissible types of "legal advertisement," which it defines as "a solicitation for legal services regarding the use of medications through television, radio, newspaper or other periodical, outdoor display, or other written, electronic, or recorded communications wherein the advertisement solicits clients or potential clients for legal services." W. Va. Code § 47-28-2(1).

59. The Act further defines "solicit" to be "an offer to provide legal services regarding the use of medications by written, recorded, or electronic communication or by in-person, telephone, or real-time electronic contact." W. Va. Code § 47-28-2(4).

60. The Act then prohibits certain conduct with respect to legal advertisements and requires several disclosures. *See id.* § 47-28-3(a).

61. For example, it prohibits the use of the word "recall" in connection with a product unless the recall was ordered by a government agency or was the product of an agreement between the manufacturer and a government agency. *Id.* at §47-28-3(a)(4).

62. The Act prohibits "[d]isplays [of] the logo of a federal or state government agency in a manner that suggests affiliation with the sponsorship of that agency. *Id.* at §47-28-3(a)(3).

63. The Act provides that, in clear and conspicuous presentation:

> A legal advertisement soliciting clients for legal services in connection with a prescription drug or medical device approved by the U.S. Food and Drug Administration shall disclose that the subject of the legal advertisement remains approved by the U.S. Food and Drug Administration, unless the product has been recalled or withdrawn.

Id. at § 47-28-3(b)(2).[1]

64. In addition, the Act provides that, in clear and conspicuous presentation:

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[1] Although this provision purports to cover legal advertisements pertaining to both prescription drugs and medical devices approved by the FDA, the definitional section of the Act states that a "legal advertisement" is one that solicits clients "for legal services regarding the use of *medications*," and not for medical devices. The disclosure requirement thus contradicts the Act's definitional section about the scope of legal advertisements covered and purports to require disclosure for legal advertisements that only solicit legal business in connection with a defective medical device, even though these advertisements are not legal advertisements within the Act's definition.

> A legal advertisement soliciting clients for legal services in connection with a prescription drug or medical device approved by the U.S. Food and Drug Administration shall include the following warning: "Do not stop taking a prescribed medication without first consulting with your doctor. Discontinuing a prescribed medication without your doctor's advice can result in injury or death."

Id. at § 47-28-3(b)(1).[2]

65. The Act also prohibits any legal advertisement that, among other things, fails to identify itself as a paid advertisement; fails to identify the sponsor of the advertisement; fails to identify the lawyer or firm that will represent clients; presents itself as a "consumer medical alert," "health alert," "consumer alert," "public service health announcement," or "substantially similar phrase." *Id.* at § 47-28-3(a).

66. Any knowing and willful violation of these requirements of the Act is "an unfair and deceptive act or practice in violation of § 46A-6-101 *et seq.* of this code" (*i.e.*, the West Virginia Consumer Credit and Protection Act).

67. The Act takes effect ninety days after its passage (*i.e.*, on June 5, 2020).

THE FIRST AMENDMENT

68. "The First Amendment, as applied to the States through the Fourteenth Amendment, protects commercial speech from unwarranted

[2] As with the prior provision, this provision purports to cover both drugs and medical devices despite the Act's definition of a legal advertisement to be one focused solely on legal services for medications.

governmental regulation." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 561 (1980) (citation omitted).

69. Moreover, "advertising by lawyers [is] a form of commercial speech entitled to protection by the First Amendment." *Peel v. Attorney Registration & Disciplinary Comm'n of Illinois*, 496 U.S. 91, 100 (1990) (plurality opinion); *Shapero v. Kentucky Bar Ass'n*, 486 U.S. 466, 472 (1988) ("Lawyer advertising is in the category of constitutionally protected commercial speech."); *In re R.M.J.*, 455 U.S. 191, 199 (1982) (holding that "lawyer advertising [is] a form of commercial speech, protected by the First Amendment").

70. The First Amendment protects commercial speech because "[c]ommercial expression not only serves the economic interest of the speaker, but also assists consumers and furthers the societal interest in the fullest possible dissemination of information." *Cent. Hudson*, 447 U.S. at 561–62.

71. Legal advertising, like all commercial speech, "serves individual and societal interests in assuring informed and reliable decisionmaking." *Bates v. State Bar of Arizona*, 433 U.S. 350, 364 (1977). It "may often carry information of import to significant issues of the day" and "serves to inform the public of the availability, nature, and prices of products and services, and thus performs an indispensable role in the allocation of resources in a free enterprise system." *Id.*

72. "The First Amendment's concern for commercial speech is based on the informational function of advertising." *Cent. Hudson*, 447 U.S. at 563.

73. For these reasons, "[t]he State must assert a substantial interest to be achieved by restrictions on commercial speech," and "the regulatory technique must be in proportion to that interest." *Id.*

74. In short, "[t]he limitation on expression must be designed carefully to achieve the State's goal." *Id.* The law must be "narrowly drawn" and "may extend only as far as the interest it serves." *Id.* at 565; *In re R.M.J.*, 455 U.S. at 203 ("Although the potential for deception and confusion is particularly strong in the context of advertising professional services, restrictions upon such advertising may be no broader than reasonably necessary to prevent the deception.").

75. Mandatory disclosures are subject to the same First Amendment scrutiny. *See, e.g., Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985). In particular, "unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech," and an advertiser's rights are "adequately protected" only if those "disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." *Id.*

76. In the First Amendment context, a law is unconstitutionally overbroad if a substantial number of its applications are unconstitutional. *United States v. Stevens*, 559 U.S. 460, 473 (2010).

77. The First Amendment jurisprudence is also sensitive to vague statutory terminology because "a vague statute ... operates to inhibit the exercise of [First Amendment] freedoms ... [and] inevitably lead citizens to steer far wider of

the unlawful zone ... than if the boundaries of the forbidden areas were clearly marked." *Grayned v. City of Rockford*, 408 U.S. 104, 109 (1972) (footnotes and internal quotation marks omitted).

THE FOURTEENTH AMENDMENT

78. At its most basic level, the Fourteenth Amendment's Equal Protection Clause requires that similarly situated persons be treated alike. *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 439 (1985).

79. When intertwined with the commands of the Equal Protection Clause, "statutes affecting First Amendment interests [must] be narrowly tailored to their legitimate objectives," and cannot discriminate against the point of view, however controversial, of one speaker as opposed to another. *Police Dep't of City of Chicago v. Mosley*, 408 U.S. 92, 101, 96 (1972).

80. Moreover, a government regulation that discriminates among speech-related activities must "be finely tailored to serve substantial state interests, and the justifications offered for any distinctions it draws must be carefully scrutinized." *Carey v. Brown*, 447 U.S. 455, 461-62 (1980).

THE ACT VIOLATES THE FIRST AMENDMENT

81. Here, the Act violates the First Amendment by imposing prohibitions and requiring disclosures that are unrelated to any State interest in preventing consumer deception and by censoring truthful representations.

82. For example, the Act prohibits the use of the term "recall" "when referring to a product that has not been recalled by a government agency or through

an agreement between a manufacturer and government agency." W. Va. Code § 47-28-3(a)(4).

83. The vast majority of recalls occur without a government agency order or an agreement between the agency and the manufacturer.

84. In fact, as the FDA defines it, a "recall is a *voluntary action* taken by a company at any time to remove a defective drug product from the market." FDA, Drug Recalls, available at https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls. *See also* 21 C.F.R. § 7.40(a) ("Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective.") (emphasis added).

85. The FDA further states that "Drug recalls may be conducted on a company's own initiative or by FDA request." FDA, FDA's Role in Drug Recalls, available at https://www.fda.gov/drugs/drug-recalls/fdas-role-drug-recalls.

86. Despite the Act's prohibition on the use of the term without a government agency order or agreement, a voluntary recall by a manufacturer is still a recall when the product violates federal law. *See* 21 CFR § 7.46(a).

87. When the manufacturer issues a recall, that manufacturer must communicate with "directly affected accounts" in a written document with the words "conspicuously marked, preferably in bold red type, on the letter and the envelope: "drug [or food, biologic, etc.] recall [or correction]." 21 CFR § 7.49(b).

88. A manufacturer may voluntarily recall either a drug or a medical device without participation in the recall by a government agency. *See, e.g.*, H.R. Rep. No. 94–853, at 8 (1976) ("Significant defects in cardiac pacemakers have necessitated 34 voluntary recalls of pacemakers, involving 23,000 units, since 1972.") (quoted in *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 337 n.5 (2008)).

89. A recall initiated by the manufacturer at the request of the FDA is not a government agency order or an agreement between the agency and the manufacturer within the meaning of the Act.

90. The Act prohibits the use of the word "recall" when a legal advertisement accurately and truthfully indicates that a drug or device has been recalled solely by the manufacturer.

91. The Act further prohibits legal advertisements from using the word "recall" even when the manufacturer is required by law to label its communication a "recall."

92. The Act also prohibits a legal advertisement from advocating the recall of a drug or device that is dangerous.

93. While the Secretary of the Department of Health and Human Services has authority to issue a recall, subject to a hearing, 21 U.S.C. § 360h(e) & 21 U.S.C. § 360bbb-8d(a)(1), that authority is rarely exercised.

94. The FDA's requests, however, are not the equivalent of an order or an agreement with the manufacturers to recall a drug or device, and these requests may be refused.

95. When a drug that is adulterated or misbranded[3] in such a way that the FDA determines it should be recalled but has not, it becomes the U.S. Department of Justice's responsibility to determine whether to initiate an action and seek a court order enjoining the continued sale and distribution of the drug. *See* U.S. Dep't of Justice, Monograph, Office of Consumer Litigation 2-3 (2011), available at https://www.justice.gov/sites/default/files/civil/legacy/2011/09/06/CPB_Monograph.pdf.

96. A court that orders injunctive relief in the form of a drug recall after the Department of Justice brings an action is not a government agency. *Hubbard v. United States*, 514 U.S. 695, 699 (1995) ("[i]n ordinary parlance, ... courts are not described as 'departments' or 'agencies' of the Government."). *See also* W. Va. Code § 55-17-2 (defining "Government agency" as an entity "within the executive branch of state government.").

97. The prohibition on the word "recall" then includes situations where the manufacturer has recalled the product voluntarily, recalled it after receiving a request from the FDA (which is not an agreement), recalled the product to forestall a judicial action seeking that result, or recalled the product pursuant to a court order.

98. The prohibition on the use of the word "recall" is overbroad and prohibits the disclosure in lawyer advertising of truthful information that the public

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[3] The Federal Food, Drug, and Cosmetic Act treats drugs whose composition, production, safety, or labeling contravenes federal requirements to be "adulterated" or "misbranded." 21 U.S.C. §§ 351, 352, 353(b)(4).

deserves to know, including a voluntary recall by the manufacturer or a recall resulting from a court order, as well as advocacy of a recall.

99. In addition to its censorship of the word "recall," the Act also irrationally requires that a legal advertisement related to injuries from *medical devices* (*e.g.*, hernia mesh, orthopedic implants, pacemakers, etc.) include a statement that warns consumers continue taking *prescription medication* without consulting their doctors. W. Va. Code § 47-28-3(b)(1).

100. The requirement to warn against taking medication does not directly advance the State's interest in any of these instances and is unduly burdensome. Many individuals utilize medical devices without any requirement that they take any prescription medication or medication related to the use of the device. Indeed, the disclosure requirement is completely unrelated to the State's interest in ensuring that consumers are adequately informed about the dangers of discontinuing use of their prescription medications without the involvement of a doctor. An advertisement about a medical device simply cannot implicate this concern.

101. An advertisement that concerns medical devices without this mandated disclosure is not "inherently misleading." *See, e.g.*, *Zauderer*, 471 U.S. at 639–41 (holding that a legal advertisement that informed readers that a particular medical device had "spawned an impressive number of lawsuits" was not "inherently misleading" and, indeed, was "entirely accurate").

102. And this disclosure requirement, as applied to advertisements about medical devices, is broader than necessary to prevent the concern that animated the Legislature. *See Peel*, 496 U.S. at 107 ("In this case, as in those, we conclude that the particular state rule restricting lawyers' advertising is broader than reasonably necessary to prevent the perceived evil.") (internal quotation marks and citation omitted)).

103. Thus, the Act impermissibly burdens speech that in no way impairs the Legislature's underlying statutory concern and, for that reason, must be invalidated. *See Cent. Hudson*, 447 U.S. at 570 ("To the extent that the Commission's order suppresses speech that in no way impairs the State's interest in energy conservation, the Commission's order violates the First and Fourteenth Amendments and must be invalidated.").

104. With respect to prescription drugs, the disclosure requirement also requires the statement, which amounts to a form of medical advice, to be made even if the FDA has sent the manufacturer warning letters indicating that the drug's dangers outweigh its safe use, that the manufacturing facilities utilized for that drug must be closed because of unsanitary conditions, or that the manufacturer's failure to recall the drug has resulted in a referral to the Department of Justice to enjoin further distribution of the drug.

105. In requiring this disclosure against ceasing use of the drug, the Act then compels speech about continuing to use a drug that the FDA has deemed unsafe and thus puts the legal advertiser in a position that appears to render

medical advice beyond the lawyer's (or Legislature's) proper expertise and contrary to the FDA's position on that drug.

106. Moreover, the Act requires all legal advertisements that concern either prescription drugs or medical devices that have not been recalled or withdrawn to include a second disclosure—this time informing consumers that the drug or device in question "remains approved by the U.S. Food and Drug Administration." W. Va. Code § 47-28-3(b)(2).

107. This disclosure requirement, like the first (concerning the continuing use of a drug), is broader than necessary to advance the State's interest.

108. In particular, the requirement applies to any legal advertisement that is "connect[ed] with" a prescription drug or medical device, irrespective of whether the advertisement could lead a reasonable consumer to believe that the FDA's approval of the drug or device was in question.

109. It further requires such a statement even if the FDA has requested that the manufacturer recall the drug or requested that the Justice Department bring an action to enjoin its further sale and distribution.

110. Information in a legal advertisement that states, for example, that a particular drug or device has "spawned an impressive number of lawsuits" is not false or misleading and may, in fact, be "entirely accurate." *See, e.g.*, *Zauderer*, 471 U.S. at 639-41. Such a statement does not suggest that FDA approval is wanting or that a recall has occurred and, again, cannot implicate the State's apparent concern.

111. In fact, FDA approval of a drug or medical device is not a guarantee that the product is safe for all users or that its warnings are complete, which is why civil lawsuits for injuries resulting from adulterated or misbranded drugs or devices are not preempted and often will identify problems with a drug or device that the FDA's review of manufacturers' information does not uncover. *See, e.g., Wyeth v. Levine,* 555 U.S. 555, 581 (2009); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501 (1996).

112. The required disclosure that a drug or device is approved by the FDA may misleadingly suggest to the public that the drug or device is safe for their use, a determination that cannot be made on the basis of listening to a legal advertisement.

113. The required disclosure may also be dangerous to the public. For example, opioids remain approved by the FDA, yet have spawned what FDA Commissioner Scott Gottlieb, M.D. called "one of the largest and most complex public health tragedies that our nation has ever faced" and "the biggest public health crisis facing the FDA." Statement of FDA Commissioner Scott Gottlieb, M.D. on the Agency's 2019 Policy and Regulatory Agenda for Continued Action to Forcefully Address the Tragic Epidemic of Opioid Abuse (Feb. 26, 2019), available at https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-2019-policy-and-regulatory-agenda-continued.

114. The still-approved disclosure is required even if the drug or device is the subject of multiple FDA warning letters and investigations and an action

brought by the United States Department of Justice, seeking an injunction against the continued sale and distribution of an adulterated drug or device. *See, e.g., United States v. Medtronic, Inc.*, Civil No. 015-cv-2168 (D. Mn., filed Apr. 27, 2015), available at https://www.justice.gov/file/414351/download.

115. Under those circumstances, it would be misleading and deceptive to include a disclaimer that, despite these actions by the Federal Government, the drug or device remains "approved" by the FDA.

116. In *toto*, the required disclosures unreasonably and unconstitutionally burden a legal advertiser's protected commercial speech rights by commandeering either too much time or too much space in what is typically a 30-second television advertisement.

117. Separately, the Act also prohibits the use of "consumer medical alert", "health alert", "consumer alert", "public service health announcement", or a *"substantially similar phrase"* (emphasis added) in a lawyer's advertisement about a drug or medical device to avoid suggesting that it is offering "professional" services, "rather than legal services. W. Va. Code §47-28-3(a)(2) (emphasis added).

118. Legal services are "professional" services being offered through such an advertisement is offering, rendering the prohibition vague and self-contradictory.

119. Legal services are available to consumers of drugs and devices, just as they are available to consumers of a wide variety of products and services that do not carry similar restrictions.

120. The restrictions on the use of these terms, even if the advertisement is quoting an FDA alert carrying those terms or displaying an FDA letter on its letterhead with its logo that states the same thing, are overbroad and inherently vague about what terms are prohibited so as to violate the First Amendment.

121. Plaintiffs are also uncertain about what terms the Act would permit, given its prohibition on "substantially similar phrase[s]."

122. Because the Act's requirements are broader than necessary to protect the State's purported interest and, indeed, are unjustified by that interest and unrelated to it, restrict truthful speech, and impose vague regulations of speech, the Act violates the First Amendment, is unduly burdensome, and must be invalidated.

123. The specific requirements and prohibitions discussed above are simply examples of the unconstitutional provisions in the Act.

The Fourteenth Amendment

124. The Act violates the Fourteenth Amendment by treating certain speakers differently than others without a substantial justification.

125. For example, the Act imposes no similar requirements on counsel seeking to defend persons who may face civil lawsuits over the covered drugs and devices.

126. The Act also imposes no similar requirements on counsel seeking to represent other potential plaintiffs where drugs and medical devices may be implicated.

127. The Act also imposes no similar requirements, and cannot impose similar requirements, on out-of-state attorneys or others who may still advertise legal services in drug and device cases to West Virginia residents without abiding by the Act's restrictions and required disclaimers.

128. In failing to embrace these similarly situated participants in the legal marketplace, the Act fails to treat similarly situated persons alike.

129. The Act cannot justify this differential treatment as narrowly tailored to achieve a substantial state interest.

130. For these reasons, the entire Act violates the U.S. Constitution because many of its provisions violate the First and Fourteenth Amendments, and those provisions are not severable from the remainder of the Act.

COUNT I

Injunctive Relief

131. Plaintiffs reallege and incorporate by reference all allegations in the paragraphs above.

132. Plaintiff Bailey has found it valuable that legal advertising about Invokana occurred and continues to find it valuable that similar legal advertising on other drugs and devices occur and provide information that allows her to evaluate those that were prescribed for her or to suggest that such information might be relevant to people she knows.

133. By restricting and burdening legal advertising in West Virginia, the Act infringes on Plaintiff Bailey's First Amendment right to receive truthful, non-

misleading information about drugs or medical devices that have harmed people and might lead to litigation.

134. Plaintiff New wants to continue to use legal advertising to inform clients in need of legal representation as a result of harms suffered from prescription drugs or medical devices.

135. Plaintiff Recht wants to continue to use legal advertising to inform clients in need of legal representation as a result of harms suffered from prescription drugs or medical devices.

136. The Act infringes on Plaintiff New's and Plaintiff Recht's right to communicate truthful information about prescription drugs and medical devices that have harmed people and, by conveying knowledge of those harms, may lead to clients for each plaintiff's law firm.

137. Plaintiffs have a strong likelihood of success on the merits because the Supreme Court has repeatedly held that regulations of commercial speech, including legal advertising, cannot be broader than necessary to advance the State's substantial interests.

138. The Act's disclosure requirements and prohibitions are broader than necessary to advance the State's interest in protecting consumers and unconstitutionally prohibit the communication of truthful and non-deceptive information.

139. In this respect, the Act violates the First Amendment, as applied to the States through the Fourteenth Amendment.

140. The Act also treats these Plaintiffs differently from others similarly situated by imposing prohibitions and requirements on legal advertising that are not imposed on other advertising concerning drugs and medical devices or on other lawyers practicing in that area of law, in violation of the Equal Protection Clause of the Fourteenth Amendment.

141. If a constitutional right is being threatened, irreparable injury exists as a matter of law. Thus, Plaintiffs will suffer an irreparable injury as soon as the Act takes effect and will continue to suffer that irreparable injury in the absence of a permanent injunction.

142. Other remedies available at law, such as monetary damages, are inadequate to compensate for the injury, which includes the violation of Plaintiffs' constitutional rights.

143. Issuance of the permanent injunction would not cause substantial harm to others. No substantial harm exists in the enjoinment of a law where the constitutional violation alleged is found to have occurred.

144. Balancing the hardships between the parties, the requested remedy in equity is warranted.

145. The public interest is served by issuance of the permanent injunction to prevent the continued violation of a constitutionally guaranteed right.

146. Accordingly, a permanent injunction should be issued here.

COUNT II
Declaratory Relief

147. Plaintiffs reallege and incorporates by reference all allegations in the paragraphs above.

148. Under the facts alleged herein, an actual, justiciable, and substantial controversy exists between Plaintiffs and Defendants, who are adverse in legal interests.

149. Plaintiff Bailey is uncertain about whether she will be able to continue to receive information about potentially harmful drugs and medical devices through legal advertisements because of the burdens and requirements imposed by the Act, burdens on information that are not imposed on any other injured person who seeks legal representation.

150. Plaintiffs New and Recht are uncertain about their rights to advertise without the burdens and requirements imposed by the Act and about the requirements for compliance, with respect to truthful, non-deceptive advertising that he has and will undertake and about how to comply with vague or contradictory provisions of the Act that also render it unconstitutional.

151. The uncertainty, discrimination against the subject matter and content of their plans for and existing legal advertising, and the burdens that the Act imposes violate Plaintiffs contravene their First and Fourteenth Amendment rights.

152. Plaintiffs New and Recht are lawyers who advertise, and the Act's requirements violate Plaintiffs' constitutional right to communicate truthful, non-misleading information in its advertising based on its imminent effective date and likely enforcement.

153. Plaintiffs seek declaratory relief based on the specific and live grievance alleged—namely, the deprivation of constitutionally guaranteed rights.

154. The controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

155. Plaintiffs request that the Court declare the Act invalid and unenforceable because it violates either the First or Fourteenth Amendments of the United States Constitution, or both. *See* Fed. R. Civ. P. 57; 28 U.S.C. §§ 2201, 2202.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs Recht, Bailey and New respectfully request that the Court enter judgment in their favor and against Defendants in their official capacities, as follows:

1. Declare that the Act is invalid and unenforceable in its entirety because it violates the First Amendment and/or Fourteenth Amendment to the United States Constitution;

2. Issue an Order permanently enjoining Defendants from enforcing the Act and ordering Defendants' compliance with the United States Constitution;

3. Award Plaintiffs all costs and fees incurred in bringing this action to the extent permitted under applicable laws; and,

4. Award all other relief as deemed just and proper.

DATED: May 4, 2020

Respectfully submitted,

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